

REMARKS

In the outstanding Office Action, Claims 5-11 were rejected under 35 U.S.C. §112, second paragraph. Claims 1-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,925,073 to Chastain et al. in view of either U.S. Patent Number 6,321,123 to Morris or U.S. Patent Number 5,683,445 to Swoyer. Claims 1-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Chastain et al. Claims 1, 2, and 4-13 were rejected under 35 U. S. C. 103(a) as being unpatentable over Swoyer in view of Chastain et al. Reconsideration is respectfully requested.

Priority

The present application is a continuation of U.S. Patent Application Serial Number 09/457,277, which is a CIP of U.S. Patent Application Serial Number 09/196,898. Furthermore, the '277 Application incorporated by reference the '898 Application, and therefore included all of the subject matter of the '898 Application. Any disclosure in the present application that was not present in the '277 Application is found in the '898 Application, which was incorporated by reference in the '277 Application. Therefore, the present application is a continuation of the '277 Application.

Rejection Under 35 U.S.C. 112

Claims 5-11 were rejected under 35 U.S.C. §112, second paragraph. By this amendment, Claims 5, 6, and 9-11 have been amended to address the rejection.

Rejections Under 35 U.S.C. 103(a)

Firstly, it is respectfully submitted that the Morris reference is not a proper prior art reference. Applicants' pending application claims priority back to U.S. Patent Application Serial Number 09/196,898, which was filed on November 20, 1998. Support for all limitations of pending Claim 1 is found in that application

(see, for example, Figure 3A of the '898 Application), and support is also found in the '277 Application since it incorporated the '898 Application by reference. Therefore, because the Morris patent was filed on March 9, 1999 (after applicants' priority date), it is not a proper prior art reference.

Applicants' claimed invention, as set forth in pending Claim 1, is directed to a coronary sinus lead that includes a lead body having at least two non-helical bends that define substantially an s-shaped portion. The lead further includes an electrode that is located distal of the s-shaped portion and is oriented toward the vessel wall.

Thus, applicants' claimed lead is designed to passively engage opposite sides of the vessel, with the electrode being directed toward a wall of the vessel.

In contrast, the Chastain et al. patent discloses a lead with a series of peaks and valleys that serve to passively fix the lead within the coronary sinus. As shown in FIG. 1, the distal portion of the lead (that carries the electrode) extends generally longitudinally and coaxially with the blood vessel, rather than being directed laterally toward a vessel wall. As described by Chastain, beginning at Column 2, line 62, the wave shape of the lead absorbs heart and respiratory motion forces, "thereby decoupling the mechanisms of dislodgment from the distal end of the lead." (Column 3, lines 2-3)(emphasis added). Thus, Chastain et al. specifically teach that the distal end of the lead is decoupled from the heart tissue to prevent dislodgment. This decoupling is achieved by forming the distal portion of the lead so that it extends longitudinally rather than laterally.

The Swoyer patent discloses a coronary sinus lead having a straight body segment and a distal end region that consists of two 45-degree bends, such that an electrode at the distal tip is directed laterally for contact with the coronary tissue. Thus, Swoyer specifically teaches a lead configured so that the distal electrode is in contact with cardiac tissue.

There is therefore no suggestion to combine Chastain with Swoyer. Chastain specifically teaches that the distal end of the lead is decoupled from the cardiac tissue, whereas Swoyer specifically teaches that the distal end is in contact with the tissue. As such, absent applicants' disclosure, there is no

suggestion to combine these references. One of ordinary skill in the art would not be motivated to combine Swoyer with Chastain et al., because those references teach completely opposite solutions.

Moreover, Chastain et al. specifically teach away from a construction in which the distal end of the lead is in contact with tissue. A reference teaches away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant. The general rule is that such a reference can not serve to create a prima facie case of obviousness. See In re Gurley, 27 F.3d 551 (Fed. Cir. 1994). Chastain et al. teach away from applicants' claimed invention by clearly leading a person of ordinary skill away from applicants' claimed invention, in which the electrode is oriented toward the vessel wall for contact therewith.

The Examiner further contends that Claims 1, 2, and 4-13 are obvious over Swoyer alone. However, there is no suggestion in Swoyer that it be modified as suggested by the Examiner. In the first place, Swoyer does not disclose or suggest any anchoring structure that is proximal of the distal electrode and that engages diametrically opposed sides of a vessel. Rather, Swoyer discloses a straight lead section 53 that contacts the vessel along one side of the vessel, as well as along the entire length of lead section 53. This design is undesirable in that not only does it engage only one side of the vessel, it also spreads the contact force over a large distance, and therefore cannot effectively stabilize the lead in a short segment of cardiac vein. On the other hand, applicants' claimed lead provides closely-spaced bends that function as substantially point contacts to allow for stabilization in short segments of cardiac vein, and that also engage diametrically opposed sides of the vessel. This disadvantage of Swoyer is highlighted by the fact that Swoyer teaches the inclusion of a separate anchoring sleeve 7 to secure the lead in place.

Thus, it is respectfully submitted that all pending claims are allowable over the cited references, for the reasons set forth above.

CONCLUSION

In view of the foregoing, it is respectfully submitted that all of the pending claims patentably distinguish over the cited references, and a Notice of Allowance is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attachment is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Respectfully submitted,

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Date

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

5. (Amended) The lead system, as defined in Claim 1, wherein the lead body further comprises a ring electrode located [at least] one of before, after, and on the at least two non-helical bends.
6. (Amended) The lead system, as defined in Claim 2, wherein the at least two non-helical bends are dimensioned to passively anchor the lead in [at least] one of the coronary sinus vein, great cardiac vein, left marginal vein, left posterior ventricular vein, and small cardiac vein.
9. (Amended) The lead system, as recited in Claim 6, wherein the [at s-shaped portion comprises a first hump and a second hump] non-helical bends are substantially in the same geometric plane.
10. (Amended) The lead system, as recited in Claim 6, wherein the [s-shaped portion comprises a first hump and a second hump] non-helical bends are substantially in different geometric planes.
11. (Amended) The lead system, as defined in Claim 1, wherein the [s-shaped portion comprises a first hump and a second hump, each of the humps comprising] non-helical bends comprise two sides forming an angle in the range of about 30 - 150 degrees.